TESTIMONY OF

Bruce Lott
Vice President of State Government Relations
Mylan Inc.

Good morning. Thank you for the opportunity to speak with you today.

My name is Bruce Lott and I am the Vice President of State Government Relations for Mylan Inc. Mylan is a leading U.S. based manufacturer of generic and specialty medications. We have facilities in eight states, as well as Puerto Rico, and provide generic medicines in more than 150 countries and territories worldwide.

Food allergies, which can sometimes lead to a life-threatening allergic reaction, or anaphylaxis, are a large and growing public health problem.[1,3] Today, an estimated one out of 13 children in the U.S. has a food allergy, a considerably higher number than previously known.[2]

We support Senate Bill 61, but would like to suggest some provisions to make it more effective at ensuring that Connecticut schools are well prepared in the event of a student experiencing an anaphylactic reaction at school. Schools nationwide have made efforts to reduce exposure to allergens in the school environment—a critical first step in managing the risk of life-threatening allergic reactions. While practicing allergen avoidance is imperative, accidental contact can still happen, which is why it is important that epinephrine auto-injectors are accessible.

Over the past two years, there have been tragedies at schools around the country that resulted in the death of a student from anaphylaxis from exposure to an allergen. Deaths in Illinois (in 2011) and Virginia (in 2012) resulted in significant attention to the issue and much discussion on how to best address it. At least 10 other states are currently considering legislation similar to the legislation we are here to support today.

A Mylan subsidiary, Mylan Specialty, markets and distributes one of several epinephrine auto-injectors in the United States. Mylan Specialty has long-standing relationships with a number of leading patient advocacy organizations, working closely on educational and awareness efforts relating to food allergies and anaphylaxis. We look forward to working with this committee, the Legislature and school officials as you work to address this important issue.

In December 2010, the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first-line treatment

for anaphylaxis.[5] Epinephrine works to relieve the life-threatening symptoms of anaphylaxis, giving affected individuals more time to seek additional emergency medical treatment.[6]

Common side effects of epinephrine may include upset stomach, vomiting, sweating, dizziness, nervousness, weakness, pale skin, headache and shaking. Although uncommon, some side effects can be serious. These include difficulty breathing and pounding, fast, or irregular heartbeat. [6]

The more rapidly anaphylaxis develops, the more likely the reaction is to be severe and potentially life-threatening. Prompt recognition of signs and symptoms of anaphylaxis is crucial. If there is any doubt, it is generally better to administer epinephrine.[7] Failure to administer epinephrine early in the course of treatment has been repeatedly implicated with anaphylaxis fatalities.

The NIH-NIAID guidelines also state that antihistamines are not effective in treating the symptoms of anaphylaxis. The use of antihistamines is the most common reason reported for not using epinephrine and may place a patient at significantly increased risk for progression toward a life-threatening reaction.[5]

The Illinois Legislature passed legislation to allow schools to stock epinephrine auto-injectors for use in response to an anaphylactic emergency. The new Illinois law allows school nurses to administer an epinephrine auto-injector to a student regardless of whether the student has been previously diagnosed if the nurse believes the student is experiencing an anaphylactic reaction. The law further allows other school personnel who are designated in a student's individual health plan to administer an epinephrine auto-injector to that student.

The Virginia, Maryland and Louisiana Legislatures passed legislation last year that will require schools to stock epinephrine auto-injectors for use in response to an anaphylactic emergency. School nurses and other trained personnel are authorized to administer epinephrine auto-injectors to any student who they believe is experiencing an anaphylactic reaction.

Massachusetts addressed this issue more than a decade ago following the deaths of two students while Missouri and Kansas passed legislation more recently. Georgia passed legislation in the past session to allow school personnel to administer epinephrine auto-injectors, Rhode Island passed legislation to allow school bus drivers and monitors to administer epinephrine auto-injectors.

To our knowledge, every state, including Connecticut, now allows students who have been prescribed an epinephrine auto-injector to bring their auto-injector to school although the rules may vary among school districts. Unfortunately, some children who are at risk have never been diagnosed and do not know they could be subject to an anaphylactic reaction. Massachusetts compiles a report each year of administrations of auto-injectors in the schools. According the Massachusetts Department of Public Health, a survey conducted in 109 Massachusetts school districts from 2001 to 2003 evaluating the

use of epinephrine for anaphylaxis management in schools, found that up to 24% of anaphylactic reactions occurred in individuals who were not known by school personnel to have a prior history of life-threatening allergies. This number is particularly disturbing.

Mylan is committed to working with states on this going forward. That is why I am pleased to have the opportunity to speak with you today. We learned through our discussions with Massachusetts and Illinois officials that cost of epinephrine auto-injectors presented a challenge to school budgets. As a result, we created a program to provide up to four free epinephrine auto-injectors per school year, upon qualification, which includes having a valid prescription, to public and private kindergarten, elementary, middle and high schools in the U.S.

Most state laws are unclear in this regard, but we are pleased that more than 20,000 schools have already taken advantage of this program. There have been several cases in schools across the country in which the free epinephrine auto-injectors were used to treat an anaphylactic reaction, underscoring the positive impact of the program. We will continue to work with stakeholders including physicians, allergy advocacy organizations, school officials, school nurses, the American Red Cross and others to learn more about the ways to address potentially life-threatening food allergies and anaphylaxis in the schools.

There are number of important statistics that have been accumulated with regard to food allergies and anaphylaxis, but I would to mention just 5 key points here:

- Nearly 6 million or 8% of children in the U.S. have food allergies (~ one in 13).[2]
- The Centers for Disease Control and Prevention report that food allergies result in more than 300,000 ambulatory-care visits a year among children under the age of 18.[10]
- Food allergens account for 30% of fatal cases of anaphylaxis.[7]
- Anaphylaxis results in approximately 1,500 deaths annually.[11]

I would like to share with you our suggestions for provisions that we would ask you to consider adding to this bill. Our recommendations are based on input from several organizations as well as what we have seen in other states.

First, it important that school nurses and other trained school personnel to be authorized to administer an epinephrine auto-injector to an individual at school or at a school function when the nurse or designated, trained personnel believe that the individual is experiencing anaphylaxis. Seconds and minutes can make the difference for a person experiencing anaphylaxis and there may not be time for an ambulance to arrive.

Second, school systems, school nurses and trained personnel need to have Good Samaritan or some type of liability protection when acting in good faith in an emergency.

Third, schools need to have authority to stock epinephrine auto-injectors for use in emergencies regardless of whether the student has been previously diagnosed.

Fourth, it is critically important that physicians be given authority to write a prescription for an entity such as a school and not just for individuals. Based on our research, it is not clear that Nevada addresses entity prescribing in you laws or regulations.

Fifth, schools should make food allergy awareness training available to food service workers and other school personnel if possible.

My colleagues and I at Mylan would like to work with you to ensure that Connecticut schools are prepared to address anaphylaxis so that emergencies do not turn into tragedies. As I already mentioned, Mylan currently offers a program to help schools address the cost issue associated with stocking of epinephrine auto-injectors and we continue to look for additional ways that we can help.

Thank you for your time and your consideration today. I would be pleased to take any questions and to work with the committee and other interested parties as you consider this legislation.

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